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APPLICATION NO.	FILING DATE	FIRST NAME OF INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,268	09/29/2003	Michael Fantuzzi	33503/US	3101

7590 01/31/2006

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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,268

Applicant(s)

FANTUZZI, MICHAEL

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,15,18-20,22,23,32-34,36-43 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,15,18-20,22,23,32-34,36-43 and 45-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on December 20, 2005 has been received and entered. Claims 14, 15, 22, 23, 32-36, 42, 43, 45-47 and 51 were amended or canceled by Examiner's amendment in the parent case and have not been amended since that point. Claims 1, 2, 5-13, 25-31 and 44 have been canceled. No claims have been added. Accordingly, claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-51 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In view of Applicant's amendments to the claims, this rejection is withdrawn.

Claim Rejections - 35 USC § 103

Claims 14, 15, 18-20, 22, 23, 32-34, 36-43 and 45-51 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Erwin (US 2005/0025756) in view of Soft Gel Technologies, Inc. (EP 888774) and Davidson et al. (US 2004/0001874). This rejection was discussed in the previous Office action.

Applicant asserts that the claimed invention is not obvious because Erwin does not suggest encapsulating his coQ 10 solution in a soft gel capsule, and Soft Gel does not teach or suggest that rice bran oil or vitamin E dissolves coQ 10. Applicant also asserts that limonene, vitamin E and rice bran oil are three different solvents and that

there is no teaching, suggestion, expectation of success or motivation that these solvents may be used interchangeably. Applicant further asserts that it is an unexpected finding that coQ 10 can be dissolved in limonene and that that solution can be encapsulated in a soft gel capsule.

In reply, as previously discussed, Erwin discloses that coQ 10 is soluble in limonene. Thus, this finding is not unexpected. Erwin does not disclose soft gel capsules containing a solution of coQ 10, but, as previously discussed, the rejection is the combination of the teachings of Erwin, Soft Gel and Davidson et al. Soft Gel discloses a liquid formulation of coQ 10 in which coQ 10 is dissolved in rice bran oil. The liquid is then formulated as a soft gel capsule. Applicant alleges that Soft Gel does not disclose that the coQ 10 is dissolved in the rice bran oil. The reference does not use the word "dissolved" or "solubilized." But, the reference certainly implies a solution. If the coQ 10 were not soluble in the rice bran oil, a precipitate would form, or a two-phase solution would form. In that event, the liquid- the rice bran oil- could not have been manipulated to produce uniform soft gel capsules for dose control, each containing the same amount of coQ 10 and the same amount of rice bran oil, which provides the improved intestinal absorption compared to dry formulations (see p. 2, lines 31-52, and p. 3, lines 4-6). Although the two solvents, limonene and rice bran oil, have different chemical structures, both can be used to prepare solutions of coQ 10. Thus, they may be used interchangeably. It is prima facie obvious to dissolve a compound in a solvent in which the compound is known to be soluble and to use a

liquid vehicle for that compound which has been shown to be successful in formulating that compound.

Regarding the solubility of coQ 10 in vitamin E, the instant claims do not recite that coQ 10 is dissolved in vitamin E or in an antioxidant. The claims recite merely that an antioxidant or a tocopherol is a further component of the soft gel capsules (claims 20 and 51). As discussed previously, Soft Gel discloses the addition of vitamin E as a further component of its soft gel capsules (see p. 2, lines 49-52, and p. 3, lines 4-6).

Similarly, regarding the solubility of coQ 10 in fish oil, the instant claims do not recite that coQ 10 is dissolved in fish oil. The claims recite merely that fish oil is a further component of the soft gel capsules (claims 40 and 50). As discussed previously, Davidson et al. disclose that coQ 10 may be blended with fish oil and that this liquid composition may be formulated as a soft gel capsule (see paragraphs 54 and 57). As with Soft Gel, Davidson et al. do not use the words "dissolved" or "solubilized." But, because coQ 10 is miscible with fish oil, the reference implies that the coQ 10 is soluble in the fish oil. Otherwise, as in the case of Soft Gel, this liquid- the fish oil- could not have been manipulated to produce uniform soft gel capsules for dose control, each containing the same amount of coQ 10 and the same amount of fish oil.

Regarding Applicant's assertion that the encapsulation of coQ 10 in a soft gel capsule is an unexpected finding (bottom of p. 12 of the Remarks), Soft Gel and Davidson et al., as discussed above, disclose that coQ 10 may be formulated as a soft gel capsule. Thus, this finding is not unexpected. Also, as discussed previously and above, Erwin discloses that dissolving coQ 10 in limonene improves its bioavailability

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(see paragraphs 2, 5, 6, 37, 38 and 40) and Soft Gel discloses that dissolving coQ 10 in rice bran oil improves its bioavailability compared to dry, powdered formulations.

Regarding Applicant's comment (p. 6 of the Remarks, 2^d paragraph) that claim 35 was not included in the disposition of claims in the last Office action, this claim was canceled by Examiner's amendment on August 26, 2005. That is, the claim was canceled before the last Office action was written. Applicants note in their following paragraph that this claim was previously canceled. In any case, because claim 35 appears as canceled in the most recent claim set, this issue is moot.

In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

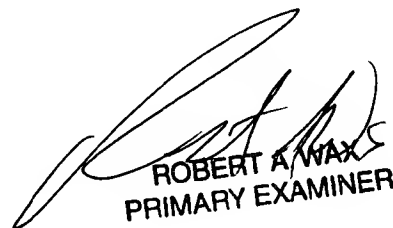
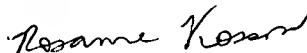
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-01-26



ROBERT A. WAX
PRIMARY EXAMINER